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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,333	12/20/1999	DOUGLAS JOSEPH DOBROZSI	7804	2248

27746 7590 02/06/2002

THE PROCTER & GAMBLE COMPANY
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EXAMINER

NGUYEN, HELEN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 02/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/467,333

Applicant(s)

DOBROZSI ET AL.

Examiner

Helen Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8 and 21-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 21-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

The amendment of paper no. 10, filed January 08, 2002, is acknowledged.

Claims 4-7 and 9-20 are canceled.

Claims 21-36 are newly added.

Claims 8 and 21-36 are pending and presenting for examination.

Claim rejection-35 USC § 112

❖ The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 21-36 are rejected under 35 U.S.C. 112, first

paragraph, because the specification, while being enabling for water as the second phase, does not reasonably provide enablement for any solvent.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. In the specification on page 12, line 1, water is disclosed. No other solvent is specified.

in spec p7 & p8

❖ The following is a quotation of the **second paragraph of 35 U.S.C. 112**:

*moot
for
cl 8.*

*moot
for cls
21-36
enablement*

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 21-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 21, the phrase "reducing agent is solubilized in a phase of

*moot
the phrase
has been deleted*
the composition other than the phase of the composition in which said active is solubilized" is vague. It is unclear as to whether the claimed composition is an emulsion, suspension or a solution.

In claim 1, the term "phase" is vague. Is the phase a solid, liquid or

*cl. 1
canceled*
gas?

In claim 1, the location of the reducing agent is unclear. Is it in the solvent or "phase other than solvent"?

moot
Claim 8 is indefinite because it depends on a canceled claim.

Claim rejection- 35 USC § 102 (b)

❖ The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-36 are rejected under **35 U.S.C. 102(b)** as being anticipated by Gallow-Torres et al. (US Patent No. 4,310,543).

Gallow-Torres et al. teach a pharmaceutical composition comprising a drug (see abstract), solvent agents including polyethylene glycol (PEG) (see abstract), and reducing agents including bisulfite, thiourea, and tert-butyl hydroquinone (TBHQ) (see column 3, lines 30, 34, 35). 0.025 to 2% weight of active drug (column 2, lines 24-25), about 90 to 99.9% weight of solvent (column 3, lines 7-8), and about 0.5% of reducing agent (column 3, line 37) are specified. Oral administration is disclosed (column 3, line 41). Water is disclosed (column 6, Table 1).

As to the claimed properties, they must be possessed by the anticipated compositions because they are the same as those claimed.

As to the claimed solubility of a reducing agent in a second phase, it is argued that the reducing agent of Gallow-Torres et al. is inherently so soluble because it is the same reducing agent as that claimed.

Claims 8, and 21-36 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Helen Nguyen
Patent Examiner

February 2, 2002

EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500